Attorney Docket: 040045-0357801

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: KLAUS PFIZENMAIER, et al.

Application No.: 10/594,189 Confirmation Number: 7771

Filed: July 13, 2007 Group Art Unit: 1647

Examiner: Bunner, Bridget E.

Title: RECOMBINANT POLYPEPTIDES OF THE MEMBERS OF THE TNF LIGAND FAMILY AND USE THEREOF

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir: I, LARRY WIESE, Ph.D., do hereby declare and state as follows:

1. I am a resident of San Diego, California, USA. My correspondence address is: 10225 Barnes Canyon Rd. A107, San Diego, California 92121. I received a Bachelor of Science degree in Physics from UCLA. I received a Doctor of Science degree in Physics from Ohio State University.

2. I am the founder and am currently the President of Therapheresis, Inc. Therapheresis, Inc. is the licensee of United States Patent Application Serial No. 10/594,189.

3. I oversee the design, development and testing of filter devices for the treatment of cancer, which incorporate recombinant proteins, and are the subject matter of United States Patent Application Serial No. 10/594,189.

4. I have reviewed the Office Action issued in connection with United States Patent Application Serial No. 10/594,189.

5. I understand that the Examiner has rejected claims 28 to 45 under 35 U.S.C. §112, first paragraph, due to an alleged lack of enablement and adequate written description.

6. I submit this Declaration to refer to studies and data in accompanying Exhibit A, as evidence that a single chain tumor necrosis factor (scTNF) comprising three TNF monomers linked together by two peptide linkers and immobilized to the surface of microporous beads performs as claimed.

7. Under my direction, Dr. Stephen Josephs, an employee of Therapheresis, Inc, having the title of Director of Binding Protein and Process Development, performed an evaluation of the filter devices incorporating immobilized recombinant human scTNF. Attached is the curriculum vitae of Dr. Josephs, which reflects his expertise in the fields of molecular biology, immunology and oncology.

8. The filter device with microporous beads with immobilized scTNF was analyzed for the removal/depletion of tumor necrosis factor receptor (TNFR).

9. First, serum or PBS spiked with TNFR was passed through the filter device. The TNFR in the serum or PBS binds to the coupled scTNF immobilized on the surface of the microporous beads in the filter device. This, in turn, leads to removal/depletion of TNFR from serum and from PBS.

10. Exhibit A shows the removal/depletion of TNFR from the serum and PBS after two dogs were previously treated with the filter devices. As illustrated in Exhibit A, the two filter devices significantly removed/depleted TNFR from the serum and PBS, by about 90%.

11. The forgoing studies and accompanying Exhibit A therefore demonstrate that the immobilized scTNF removes/depletes TNFR as claimed.

12. I therefore conclude that the filter device recited in the claims functions as claimed.

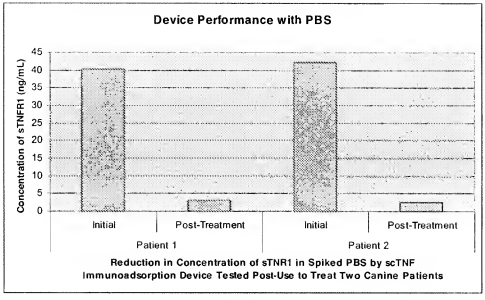
13. I further declare that all statements made herein of my own knowledge are true, that all statements mode on information and belief are believed to be true,

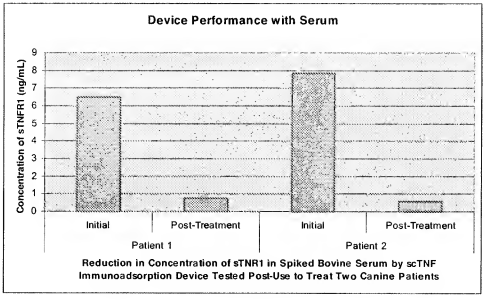
and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. §1001), and may jeopardize the validity of the application or any patent issued thereon.

Sept 27, 2011
Date

Larry Wiese, Ph.D.

EXHIBIT A





The figures above demonstrate the ability of two filter devices constructed with single chain tumor necrosis factor (scTNF) covalently immobilized to the surface of 60 micron microporous beads to remove/deplete human soluble TNF receptors (sTNFR1) in spiked phosphate buffered saline (PBS) and bovine serum. Prior to the study, both filter devices had been used to treat two canine cancer patients. The data shows that the filter devices still retained the ability to remove/deplete soluble TNFR, by approximately, 90% at flow rates comparable to those used during treatment.

Steven F. Josephs, Ph.D.

Email: sjosephs@therapheresis.com Cell: 858.663.9693

Professional Summary

Director, Binding Protein and Process Development **2005-Present**
Therapheresis, Inc., San Diego, CA

Headed the Manufacturing of Small Molecule Therapeutics responsible for contract fill and finish of formulated anti-proliferative ribozyme under clinical investigation for the treatment of psoriasis, hypertrophic scars and keloids. Wrote batch records, monitored release testing.

Associate Director, Pre-Clinical Product Development **2003-2005**
Immusol Inc., San Diego, CA

Head of Manufacturing of Small Molecule Therapeutics

Significant achievements:

1) Responsible for contract fill and finish of formulated antiproliferative ribozyme under clinical investigation for the treatment of psoriasis, hypertrophic scars and keloids. Wrote batch records, monitored release testing.

2) Design and contracting of pre-clinical safety and efficacy studies. Mouse, rat and minipig studies to support ongoing and planned clinical trials.

3) Formulation development of small molecule lead drugs. Developed three clinically relevant formulations for small molecule drug. HPLC purification and formulation of small molecules for pre-clinical animal studies.

4) Responsible for CMC section of IND regulatory submissions

Director, Process Development **1998-2002**
Genstar Therapeutics, San Diego, CA

Directed a group of four process development scientists to develop manufacturing processes for gutted adenovirus vectors for I.V. delivery of the human FVIII gene for treatment of hemophilia A and for intra-prostatic treatment of prostate cancer.

Significant achievements:

1) Developed and performed tests leading to qualification of a human cell line which was used for preparation of human clinical trial material.

2) Established a production master cell bank under cGMP conditions.

3) Set up a CellCube system for manufacture of adenovirus vectors using a proprietary human cell line.

4) Responsible for technology transfer of basic research to Phase I manufacture of clinical trial material for hemophilia A and documentation for IND submission:CMC

section.

5) Developed a scalable upstream manufacturing processes for adenovirus vectors using stirred tank bioreactor systems and suspension microcarrier beads.

6) Downstream development of chemical lysis technology for release of virus from cells and development of a rapid CsCl gradient method for purification of gutted adenoviruses.

7) Performed formulation studies studies: recovery of adenovirus from frozen storage in non-glycerol containing lyophilizable formulations. Obtained recoveries comparable to those observed using traditional glycerol containing formulations.

8) Developed and qualified lot release assays specific for the company adenovirus products including ELISA assays and tests for process residuals.

9) Participated in bringing two manufacturing facilities on line. Provided oversight of equipment validation, including reviewing/writing validation protocols, IQ, OQ and PQ. Compilation of data and writing validation reports.

Senior Research Scientist **1991-1998**
Baxter Healthcare Corporation, Round Lake, IL

Head of Virology Research in the Applied Sciences Group—performed internal contract research in viral validation studies and product development support for I.V. Systems, Hyland and Fenwal and Applied Sciences. Conducted research and development for manufacture of products related to treatment of hemophilia; Key role of this position was to construct an expression vector system for gene therapy of hemophilia A

Significant achievements:

1) Cloned and characterized a functional human FVIII cDNA

2) Generated a novel cell line for complementation of E1 deficient adenovirus vectors

3) Developed a gutted adenovirus vector capable of delivering a functional human FVIII cDNA by intravenous administration

Director, Molecular Biology **1990-1991**
Universal Biotechnology, Inc., Rockville, MD

Directed a group performing contract molecular biology services for government and private industry. Services included protein expression and purification, restriction enzyme mapping and gene characterization, molecular cloning and lambda phage library screening. Manufactured prototype molecular biology kits in collaboration with international vendors. Interfaced with clients for contracts, deliverables and reports.

Chemist **1975-1990**
National Cancer Institute, National Institutes of Health, Bethesda, MD

Significant Achievements:

1) Characterization of oncogenes: Genetic comparison of the Simian Sarcoma Virus v-sis gene to the human homologue, platelet derived growth factor (PDGF) and demonstration of the transforming potential of the normal human gene

2) Studies of the human T-cell leukemia virus—genetic characterization

3) Sequence determination and functional analyses of HIV including defining the tat gene and generation of functional clones of HIV

4) Co-discoverer of Human Herpesvirus 6 (HHV-6), the etiologic agent of Roseola; molecular characterization studies

Education

Ph.D., Chemistry, The American University Thesis in Molecular Biology (Post Speciation Acquisition of Endogenous Viruses related to BaEV in Old World Primates)	1982
M.S.S.T., Science Teaching, The American University	1977
B.A., Chemistry, Susquehanna University	1972
Licensed Board of Pharmacy Exemptee-In-Charge	2005

Honors and Special Scientific Recognition:

Aikens Chemistry Scholarship	1973-1974
Honorary Mathematics Society, Susquehanna Univ.	1973
Certificate for sustained high quality work performance, National Institutes of Health, Bethesda, MD	1978
Outstanding Young Men of America	1985
Special achievement award, National Institutes of Health, Bethesda, MD	1986
Award for outstanding work performance, National Institutes of Health, Bethesda, MD	1989
Member, New York Academy of Sciences	1988-1991
Member, Scientific Advisory Board, AIDS and Cancer Research Foundation, Beverly Hills, CA	1988
Letter of Commendation, GenStar Therapeutics Management Contributions	2002

Publications

Balague C, Zhou J, Dai Y, Alemany R, Josephs SF, Andreason G, Hariharan M, Sethi E, Prokopenko E, Jan HY, Lou YC, Hubert-Leslie D, Ruiz L, Zhang WW. Sustained high-level expression of full-length human factor VIII and restoration of clotting activity in hemophilic mice using a minimal adenovirus vector. Blood. 2000 Feb 1;95(3):820-8.

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Geng YQ, Chandran B, Josephs SF, Wood C. Identification and characterization of a human herpesvirus 6 gene segment that trans activates the human immunodeficiency virus type 1 promoter. J Virol. 1992 Mar;66(3):1564-70.

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Josephs SF, Henry B, Balachandran N, Strayer D, Peterson D, Komaroff AL, Ablashi DV. HHV-6 reactivation in chronic fatigue syndrome.
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Krueger GR, Ablashi DV, Josephs SF, Salahuddin SZ, Lembke U, Ramon A, Bertram G. Clinical indications and diagnostic techniques of human herpesvirus-6 (HHV-6) infection.
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In Vivo. 1991 May-Jun;5(3):193-9. Review.

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length transmembrane protein. AIDS Res Hum Retroviruses. 1990 Sep;6(9):1079-85.
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